Appln. No.: 10/594,473

Amendment Dated March 13, 2012

Reply to Office Action of February 15, 2012

<u>Amendments to the Claims:</u> This listing of claims will replace all prior versions, and listings, of claims in the application.

## Listing of Claims:

- 1. (Currently Amended) A process for preparing a medicament comprising the steps of:
- (a) combining a pharmaceutically active ingredient in the form of an agglomerate of primary particles having an agglomerate particle size such that the agglomerate is capable of passing through a sieve having a mesh of 50-3000  $\mu$ m with a pharmaceutically acceptable particulate carrier, and;
- (b) mixing the resultant material in a mixer to break up the agglomerate into primary particles dispersed in a pharmaceutically acceptable particulate carrier such that 90% or more of the pharmaceutically active ingredient exists as primary particles having a particle size of 50 µm or less-; and
- (c) filling the mixture from step (b) into the reservoir of a dry powder inhaler.
- 2. (Original) A process as claimed in claim 1, wherein in step (b) the pharmaceutically active ingredient is dispersed homogeneously in the pharmaceutically acceptable particulate carrier such that drug recovery from each of a plurality of samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%.
- 3. (Original) A process as claimed in claim 1 or 2, wherein prior to step (a) the pharmaceutically active ingredient is passed through a sieve having a mesh of 50-3000 µm.
- 4. (Original) A process as claimed in claim 1 or 2, wherein the agglomerate particle size is such that the agglomerate is capable of passing through a sieve having a mesh of 250-1000  $\mu$ m.
- 5. (Original) A process as claimed in claim 4, wherein prior to step (a) the pharmaceutically active ingredient is passed through a sieve having a mesh of 250-1000  $\mu$ m.
- 6. (Previously Presented) A process as claimed in claim 1, wherein the medicament is an inhalable medicament.

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- 7. (Original) A process as claimed in claim 6, wherein the pharmaceutically active ingredient is an anti-inflammatory steroid and/or a bronchodilator.
- 8. (Original) A process as claimed in claim 7, wherein the inhalable medicament is budesonide, formoterol or etiprednol.
- 9. (Previously Presented) A process as claimed in claim 1, wherein the pharmaceutically acceptable particulate carrier is lactose.
- 10. (Original) A process as claimed in claim 9, wherein the pharmaceutically acceptable particulate carrier is alpha-lactose monohydrate.
- 11. (Withdrawn) A medicament obtained by the process as claimed in claim 1.
- 12. (Withdrawn) A dry-powder inhaler containing the medicament as claimed in claim 11.
- 13. (New) A process as claimed in claim 1, wherein the reservoir is the reservoir of a multidose dry powder inhaler.
- 14. (New) A process as claimed in claim 1, wherein the reservoir is defined by a capsule.
- 15. (New) A process as claimed in claim 14, wherein the capsule, when filled, contains a unit does of active ingredient.